



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,749	01/05/2004	Kevin R. Heath	10527-118005	5630

26161 7590 10/13/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER

SWEET, THOMAS

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/751,749

Applicant(s)

HEATH, KEVIN R.

Examiner

Thomas J. Sweet

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see page 7, filed 08/21/2006, with respect to the drawings have been fully considered and are persuasive. The objection of the drawings has been withdrawn.

Applicant's arguments, see page 8, filed 08/21/2006, with respect to the rejection(s) of claim(s) 39-46 under 35 USC 112(2) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new terminology of layers.

Applicant's arguments filed 08/21/2006 have been fully considered but they are not persuasive. With regard to priority, applicant is combining plural contradictory embodiments in an attempt to support the new matter claimed. The multi-composite disclosures (from each of the continuing applications) stand alone requiring different layer materials for the three or more layers. Metal for each of the layer is not recognized as the intent of the disclosed invention. Even if it could be established that the intent of the invention was each of the layers being metal, each layer would be required to be different based on the multi-composite disclosure. With regard to the objection to the specification and rejection of the claims under 35 USC 112(1), the same argument as to lack of priority applies to the current application's disclosure. With regard to double patenting, the rejection is not a provisional rejection as stated since a patent is used in the rejection rather than an application. Claim 39 stands rejected under double patenting until properly traversed. With regard to the rejections under 35 USC 102 and 103 in view of Jacobs, the current application has been denied the priority date of July 8, 1992 so the rejections stand. With regard to the rejection under 35 USC 103 in view of Hess, in response to applicant's

Art Unit: 3738

argument that “the thickness of the reinforcing member...enhances the radiopacity of the metal member”, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In response to applicant's argument that “the second metal enhances the radiopacity of the metal member”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. With regard to the official notices, Although as stated with regard to the Hess rejection “Applicant does not concede”, applicant has not specifically point out the supposed errors in the examiner’s action, which include stating why the noticed fact is not considered to be common knowledge or well-known in the art. Therefore, the Official notices are now considered admitted prior art.

Priority

Applicant’s claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

Art Unit: 3738

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 07910631 to 09924275, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Accordingly, claims 39-46 are not entitled to priority to the prior application.

Regarding claim 39, the disclosure does not support the terminology of “third metal layer”. The disclosure mentions layers and coatings which are not described as metal such that a third layer would be enabled or reasonably recognized by one of ordinary skill in the art at the time the invention was made beyond the two layers of metal disclosed.

Regarding claims 39-46, the only disclosure of three layers is to “three or more layers” of successively less dense outer material cladded on a filament, which therefore does not support layers of the same material as required by claim 40. Likewise, in the situation of only two of the “at least two different metals” are in three layers is contradicted by this same passage which would require each to be a different material.

Specification

The amendment filed 08/21/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

Art Unit: 3738

“the third metal layer is formed of said first metal” of claim 40 is not disclosed. As discussed above with regard to priority, the disclosure is contrary to a multi-composite being of the same material in plural layers.

A “third metal layer” of claims 39-46 is not disclosed such that one of ordinary skill in the art would recognize possession the claimed limitation. The disclosure deal with layers of different densities (metal is not specifically disclosed), since other materials are specifically disclosed as a layer (coatings, such as fluorocarbons), one would not reasonable recognize a third metal layer as the invention. Since, alloys can be formed by two or more metals, the passage “at least two different metals” does not support a third metal layer.

A third metal layer associated with a sheet of claim 46 is not supported. The disclosure of a third layer is directed to a filament.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above with respect to the specification objection, the claims do not

Art Unit: 3738

reasonable convey to one of ordinary skill in the art that the application had possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-46 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the ordering of layers. The disclosure states that a multi-composite system requires more dense successive material layers to be located towards the core. Claims 39-46 do not set out an ordering of the first through third layers such that the density increase toward the core as required by the disclosure.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23 of U.S. Patent No. 6287331. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 23 encompasses the limitations of claim 39.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al (US 637123). Jacobs et al discloses a medical device, comprising: an implantable medical stent (fig. 1) expandable by a balloon to fix the stent in a predetermined position in contact with a body lumen wall by plastic deformation (col 4, lines 8-24), said stent formed of a metal member (fig. 2) in the form of a tube (as seen in fig. 1), said metal member having a cross-sectional thickness of about 0.0075 inch or less (col 4, line 38) and formed of at least two different metals (tantalum and stainless steel), said metal member including across said thickness a first metal layer (stainless steel, 18), a second layer (tantalum, 20), and a third metal layer (stainless steel, 22), wherein the first metal layer is formed of a first metal and the second metal layer is formed of a second, different metal, and wherein the density of the second metal is greater than the density of the first metal (tantalum is denser than stainless steel) for enhancing the radiopacity of the metal member (inherent, based on the structure being the same as the present invention).

With regard to claim 44, a non-metal coating on an outer surface of said metal member is inherent since chromium oxide forms as a coating on all stainless steel.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 and 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Jacobs et al. by Jacobs et al discloses a stent as discussed above. However, Jacobs et al does not disclose a polymer coating on the stent. It is admitted prior art to coat a stent with a drug polymer for the purpose of providing treatment material at the location of the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to coat the stent of Jacobs et al with a drug polymer in order to provide treatment material at the location of implantation.

With regard to claim 46, the metal member is a composite sheet form member configured in the form of a tube (as shown by figs. 1 and 2).

Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (US 5,197,978). Hess discloses a medical device, comprising: an implantable medical stent (fig. 8) expandable by a balloon to fix the stent in a predetermined position in contact with a body lumen wall by plastic deformation (figs. 1-3), said stent formed of a metal member in the form of a tube

Art Unit: 3738

(fig. 8), said metal member having a cross-sectional (at # 44) and formed of at least two different metals (shape memory alloy- abs and tantalum- col 8, line 37), said metal member including across said thickness a first metal layer (shape memory alloy, the inner wall), a second layer (44- tantalum- col 8, line 37), and a third metal layer (42- shape memory alloy, the outer wall), wherein the first metal layer is formed of a first metal and the second metal layer is formed of a second, different metal, and wherein the density of the second metal is greater than the density of the first metal (tantalum is denser than a shape memory alloy such as Nitinol) for enhancing the radiopacity of the metal member (inherent since this is the structure of the present invention). However, Hess remains silent as to the thickness of the wall (about 0.0075 inch or less). It is admitted prior art to make the stent wall as thin as possible on the order of 0.005 inch or 0.1 mm for the purpose of supporting the vessel wall but not interfering with the flow of blood. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the wall of Hess on the order of thickness of about 0.005 inches or about 0.1mm in order to supporting the vessel wall but not interfering with the flow of blood.

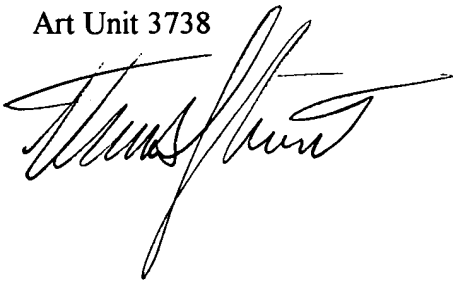
With regard to claim 40, the third metal layer is formed of said first metal (outer and inner surfaces of memory alloy).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J. Sweet whose telephone number is 571-272-4761. The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thomas J Sweet
Examiner
Art Unit 3738

A handwritten signature in black ink, appearing to read 'Thomas J Sweet', with a stylized, flowing script.